January 15, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

December 23, 1998

CERTIFIED MAIL

Michael Goodis, Chemical Review Manager
Document Processing Desk (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

SUBJECT: METHIDATHION: ENVIRONMENTAL FATE AND ECOLOGICAL EFFECTS PRELIMINARY RISK ASSESSMENT FOR METHIDATHION DATED NOVEMBER 13, 1998; 30-DAY COMMENTS

Dear Mr. Goodis:

Novartis Crop Protection, Inc. and Gowan Company are submitting this letter with 30-day comments in response to the above referenced preliminary risk assessment regarding errors, confidential business information and planned data that may be submitted during or subsequent to the 60-day comment period. In view of the complexity and amount of data to be reviewed in a relatively short period of time, if additional errors are discovered, we reserve the right to submit them during the additional 60-day comment period.

ERRORS, FORMATTING AND CLARIFICATION OF TEXT

Under "B. Status of Environmental Fate Requirements" the tentative status of studies is given starting at the bottom of page 2. At the end of comments for each study, a footnote (superscript) is given. It is difficult to link the footnote with the corresponding number in parentheses for each study starting on page 3. It is also somewhat confusing to identify the two bottom paragraphs on page 5, where each paragraph begins with numbers in parentheses which are actually unrelated to the footnotes. It is suggested the numbers in parentheses for each study starting on page 3 be replaced with numbers in superscript, the same as for the status comments.

For 165-4. Accumulation in Fish and its footnote 8 on page 3, there is no further discussion in the section for that footnote; however, but there is a data summary presented on page 15 under "164-4. Bioaccumulation in Fish" which should be 165-4. Accumulation in Fish. In the status comment on page 3 it is mentioned that a supplemental study had no MRID number, but on page 15 in the

data summary results from a “fish study 00158532” are given. It is not clear whether the studies mentioned at both places are actually the same study.

On page 11 paragraph 4 line 3, it was stated that a list of degradates identified in laboratory studies was provided in Table I including chemical names, structures and studies where identified. An unnumbered table is given on page 15 without structures. Table I and corresponding structures were unable to be located in the draft document that was received.

No other significant errors were found in our review of the preliminary risk assessment, but it was not possible to review any of the calculations that resulted in the entries given in the tables. Upon review of the technical aspects of the risk assessment and subsequent interpretations, further comments will be submitted during the 60 day comment period.

Confidential Business Information

The preliminary risk assessment does not contain confidential business information.

Planned Data

Avian reproduction studies are currently underway with a completion date approximately July 1, 1999.

60-Day Comment Period

Additional detailed responses will be provided regarding the technical aspects in the preliminary risk assessment. A major issue is the new requirement for labeling the phosphorothioate (P-S-C) portion of the methidathion molecule. It is disturbing that the agency suddenly at the last minute requires this information, since in previous reviews of the same environmental fate studies several years ago, only a casual comment was included from a single reviewer that the data “may be required”. There was no additional explanation indicating the justification for the comment. It appeared in those previous reviews that the comment was given more as an observation and not a significant concern. We will respond in more detail indicating the labeling of that portion of the molecule is not scientifically sound based on information already known. The basis of this latter statement will be supported with a review of the literature relating to the transformation of simple organophosphate and organothiophosphate esters under hydrolytic and metabolic conditions.

We look forward to meeting with the Agency as suggested in the preliminary risk assessment regarding the above issue and other additional studies the Agency is requiring. If you need additional information or clarification, you may contact me at (336) 632-2391.

Sincerely,

Robert E. M. Wurz, Ph.D.
Senior Regulatory Manager
Regulatory Affairs